Radiodiagnostic Imaging Affiliates

Jane A.
Action
Rec'd 9/21/82
EA 82-105
DCS

30-19449

September 17, 1982

Mr. Richard C. DeYoung
Director
Office of Inspection &
Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

RE: License No. 41-19870
EA 82-105

Dear Mr. DeYoung:

I am enclosing my reply to the Order to Show Cause and Order Modifying License dated August 17, 1982. I sincerely hope that the Commission will find my responses satisfactory and will see cause why my license should not be revoked.

Sincerely,

Charles C. Self
President
R.I.A. of Virginia, Inc.

CCS:eh

Enclosure: Reply to Order
to Show Cause and Modify
License.

cc w/o encl: J.P. O'Reilly
Regional Administrator
Region II

H.M. Mobley, Director
Division of Radiological Health
Tennessee Department of Public Health

C.R. Price, Supervisor
Bureau of Radiological Health
Virginia Department of Health

IE-14

2500 21st Avenue South, Nashville, Tennessee 37212 (615) 297-7726

Mr. Nelson Hobbs
Technologist
R.I.A. of Virginia, Inc.

Dr. Subhash Saha
Radiation Safety Officer
R.I.A. of Virginia, Inc.

Dr. Shiv Navani
Radiologist
Lonesome Pine Hospital

Mr. Tom Rice
Administrator
Lonesome Pine Hospital

Mr. Ron Bodary
Administrator
Lee County Community Hospital

Sister Ann Christina
Administrator
St. Mary's Hospital

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In the Matter of

Radioidagnostic Imaging
Affiliates,of Virginia, Inc.
2500 21st. Avenue South
Nashville, Tennessee 37212

Byproduct Material
License No. 41-19870-01
EA 82-105

REPLY TO

ORDER TO SHOW CAUSE AND ORDER MODIFYING LICENSE

I, Charles C. Self, do hereby make the following written statement in answer to an Order to Show Cause and Order Modifying License dated August 27, 1982.

I am the president of Radiodiagnostic Imaging Affiliates, Incorporated located at 2500 21st. Avenue South, Nashville, Tennessee and have served in this capacity since September, 1978. I am also the President of Radiodiagnostic Imaging Affiliates of Virginia, Incorporated which provides nuclear medicine services to three hospitals in the Southwest section of Virginia.

I will reply to the sections as numbered in the Show Cause Order.

1. The surveys were not performed due to the fact that we did not have the proper survey instruments. There are several reasons that the survey meters were not available and in place:
   a. A survey instrument was ordered but did not meet the requirements of the N.R.C.
   b. From the inception of the company, Mr. James L. Winfree, a partner,

was in charge of the day to day activities of the Virginia operation. From inception, Mr. Winfree embezzled the money from the company. He repeatedly told the technologist, Mr. Nelson Hobbs, not to communicate with me nor make requests to me since he, Mr. Winfree, was the manager of that area. Mr. Hobbs has since told me that he made more than twenty requests to Mr. Winfree for the instruments and other supplies necessary to adequately perform his job.

Mr. Winfree did not relay these requests to me since I would have then known that the money we had invested had been embezzled. I am enclosing the only bank records that I have been able to obtain showing that of all the checks written on the account, only the ones circled have anything remotely to do with R.I.A. of Virginia. In addition, the initial statement only shows a deposit of $4,000.00 The original deposit should have been $16,000.00. Obviously, the embezzlement started from the beginning.

My association with Mr. Winfree has been a long and pleasant one until this point. We had been friends for 15 years. He also had a tremendous business reputation in Nashville and Tennessee. I simply made a mistake in judgment based on the above information.

Mr. Winfree has since filed bankruptcy, and his wife is in the process of divorcing him. I have been unable to locate Mr. Winfree

since the inspection by the N.R.C. on August 12, 1982.

c. We have taken corrective actions since the inspection of August 12, 1982. They are as follows:

1. Ordered and received all required survey instruments. These were paid for with personal funds.
2. All required surveys have been and continue to be done routinely.
3. Dr. Subhash Saha has been named Radiation Safety Officer and is auditing and filing results of these surveys.
4. I have been actively involved in the day to day operations of the business. I am in daily contact with the technologist, Dr. Saha or both , verifying that all surveys are done and the information is properly recorded.
5. Have held a safety meeting at Lonesome Pine Hospital with Doctors Saha and Navani, Mr. Tom Rice, the Chief Radiology Technician, Mr. Hobbs and myself in attendance.
6. Have scheduled safety meetings at the other two hospitals.
7. Dr. Saha and the technologist meet daily to insure surveys are being done.

2. The molybdenum - 99 breakthroughs were done until June 10, 1982. I had previously thought that I picked up the kit necessary to do the tests. However, Mr. Hobbs said that Mr. Winfree picked up the kit while he was out of the office and Mr. Winfree returned it to Nashville.

I had ordered the dose calibrator for use in Virginia. In the past, when I have ordered dose calibrators for R.I.A. here in Tennessee, the breakthrough kit was automatically shipped. This order was placed through a new vendor which sells the kit as an accessory. Neither the salesman nor I was aware of this. When we discovered that it was not shipped with the calibrator, he placed an order for the kit but we never received it and haven't to this date. I later ordered and received a kit directly from the manufacturer.

My knowledge of the importance of the moly breakthrough was limited but I now know and understand why it is important and necessary.

Again, corrective actions have been taken. They are as follows:

1. All personnel have read and understand 10CFR 35.14(b)(4)(ii)
2. Breakthrough kits have been ordered and received.
3. Checks are being made as the license requires.
4. Dr. Saha is monitoring and filing results of these checks.

3. The Condition 12 of the license was simply misunderstood by everyone in the company and the named physicians. In the 26 hospitals in which we are licensed in Tennessee, the technolgist routinely injects the doses. I have tried to reconstruct my initial conversation with Dr. William Walker and Mr. Francis St. Mary as has Mr. Wayne Coffman, who attended this meeting with me, and neither of us recalls a condition of our

License being that the named physicians do the injections. At the meeting held in Atlanta, on August 23, 1982, in which Mr. St. Mary was in attendance and Dr. Walker was listening on a telephone hook-up, neither of them could recall telling us that the physicians had to inject.

Since that meeting, Mr. Phil Cahmbliss, N.R.C. Inspector, has told Mr. Hobbs, our technologist, that there are at least 80 other licensees in which this condition is stated exactly as ours and that the technologists are routinely doing the injections and that none of these have been cited.

Our corrective actions are that the physicians are injecting the doses at Lee County Hospital and Lonesome Pine Hospital. We were given permission for the tech to inject at St. Mary's Hospital in the presence of the physician since the physician is pregnant.

4. The failure to abide by Condition 17 resulted from several factors as listed:

   a. The technologist felt that the storage of the Xenon at the vent which is in an unshielded window created more of a hazard than storing the Xenon adjacent to the vent within the shielding provided by the lead bricks.

   b. The fire marshall would not allow a vent in the door opening onto

a hallway. This placed us in somewhat of a Catch 22 position. If we followed N.R.C. requirements, we violated the fire codes; if if followed the fire codes, we violated the N.R.C. requirements.

c. The drawings submitted with cut license were provided by the owner of the property. I was remiss in not checking to see that everything was as indicated.

We have taken the following corrective measures:

1. Ordered a lead box just for Xenon storage that can be located directly in front of the vent.
2. Have secured a new location for our hot lab in Pennington Gap, Virginia. (Drawing enclosed) The building is in property owned by the City of Pennington Gap, Virginia and is located on the second floor with no other offices being located on that floor.

5. The primary reasons that the daily constancy checks were not done are as follows:

   a. The technologist did not understand this requirement for daily checks. Most of his experience has been working in Tennessee and this was not a requirement of that license.

   b. Sources were not available due to the above mentioned financial problems.

   c. Again, when calibrators have been ordered in the past, all sources were shipped with calibrators. This vendor again lists it as an

accessory and neither the salesman nor I was aware that sources had not been shipped with the calibrator.

d. Mr. Hobbs did use a back-up system. There were two dose calibrators in the hot lab and he routinely checked the dose on both to insure the accuracy of the dose. It would have been highly unlikely that both calibrators would have been out of calibration exactly the same degree.

Corrective actions include the ordering and receipt of constancy check sources. These are being performed daily with copies supplied to Dr. Saha for his inspection and filing.

6. On the date of inspection, a package containing a spent generator was packaged for return and labeled with a Yellow II. However, the inspection was done on a Thursday when the radiation level on one surface exceeded 68 mrem/hr, thereby requiring a Yellow III label. The generator would have been mislabeled had it been shipped back that day. However, the generators are always picked up on late Saturday night or early Sunday morning. This being the case, the generator would certainly have been well within the 50 mrem/hr range or less

However, we now have taken an additional corrective action. We have ordered and received a second generator shield enabling us to store the generator safely for two weeks prior to its return.

7. On the date of inspection, the radiation level measuring 1.2 mr/hr was due to the return generator, which had been packaged that day, being in the middle of the lab. We have since ordered and received an additional generator shield allowing us to wait two weeks to return one generator. At the present we are constantly measuring .1 mr/hr at 3 feet distance - well within the N.R.C. requirements.

8. The contamination at St. Mary's Hospital was and continues to be a dilemma. Using the camera, uncollimated, the technologist routinely scanned the room for any radiation prior to leaving each day. This was done on August 17, 1982. Yet when the inspector found this contamination in the trash can, we could not dispute his finding. Our technologist was notified at 10:00pm of their findings. Early the next morning at 6:00 am, he returned to St. Mary's, investigated the room and the trash can and found no evidence of a wet paper towel that had been contaminated. The trash had not been emptied overnight. Futhermore, this reported contamination represented no hazard to the public nor to hospital personnel since it was in a locked room that is accessible only to 3 people with keys. We interviewed anyone that had access to the area and no one could explain the disappearance of the paper towel.

However, the technologist now carries a disposal bag with him on each call and stores anything that is used in that hospital while he is

there. Upon leaving, he ties, labels the bag and transports it back to the hot lab for decay. He also surveys the room completely and records these surveys prior to leaving.

9. 10 CFR 19.11 does require that the licensee post certain items. Some of these are notices to employees. Since Mr. Hobbs was the only employee at the office, we felt that he would know where the required materials were filed.

   After consultation with Mr. Chambliss, we now have the required notices posted with information that the current copy of our license and Part 19 and 20 of the regulations are filed in the desk in the hot lab.

In summary, we petition the Commission to allow our continued operation for the following reasons:

1. Being a small business, it was indescribably difficult to overcome the lack of management and embezzelment of our funds by Mr. James Winfree.
2. We have made the changes noted in Section III of your order and they are working well.
3. We have been and will continue to make every effort to meet not only the letter but the spirit of each Commission requirement.
4. I have asked and I have been told by more than one person from the Commission that at no time did we represent a health hazard to our patients or to the community at large.

5. We have been inspected weekly since our initial inspection with no citations being issued.

6. As your Commission personnel will report, we have brougnt a much needed service to a medically under served area. Prior to our starting service in the area, patients were transported, in some instances, over great distances for the scans to be performed. The other alternative has been to use other more expensive and time consuming diagnostic tests to obtain the same clinical results.

   Without exception, the radiologists and hospital administrators have been very supportive of our continued service in the area. They have pledged to help in anyway that they can to see that we continue to meet all Commission requirements.

7. I personally pledge to the Commission that I will spend whatever amount of time and resources necessary to guarantee the continued operation of our license within the guidelines of the Commission.

If these answers to the Show Cause Order are not acceptable to the Commission, I hereby request a formal hearing to be held at your earliest convenience.

Charles C. Self

R.I.A. of Virginia, Inc.
Charles C. Self
President

Subscribed and sworn to before me on this 17th day of September, 1982, Nashville, Tennessee.

Katherine Smith
Witness

My Commission Expires July 21, 1985

DDA 1799
(7-81)

THE PEOPLES BANK

LEBANON - NORENE - MOUNT JULIET

DATE LAST STATEMENT	MINIMUM BALANCE	AVERAGE BALANCE	NUMBER OF DAYS	NO. DEBITS THIS STMT.	NO. CREDITS THIS STMT.	NO. DEBITS THIS MONTH	DATE THIS STATEMENT
		27	23		1		11 30 81 1138

BALANCE LAST STATEMENT	TOTAL CREDITS	TOTAL CHECKS	SERVICE CHARGE	BALANCE THIS STATEMENT
	400000			400000

RIA OF VIRGINIA INC
311 PLUS PARK BLVD
SUITE 120
NASHVILLE TN 37217

01

900-481-3
ACCOUNT NO.

CHECKS AND OTHER DEBITS	DEPOSITS AND OTHER CREDITS	DATE	BALANCE
	400000	13	400000

$20,463

DDA 1799
(7-81)

THE PEOPLES BANK

LEBANON - NORENE - MOUNT JULIET

DATE LAST STATEMENT	MINIMUM BALANCE	AVERAGE BALANCE	NUMBER OF DAYS	NO. DEBITS THIS STMT.	NO. CREDITS THIS STMT.	NO. DEBITS THIS MONTH	DATE THIS STATEMENT
1130	20	32	31	7	2	5	123181059

BALANCE LAST STATEMENT	TOTAL CREDITS	TOTAL CHECKS	SERVICE CHARGE	BALANCE THIS STATEMENT
400000	167339	238930		328409

RIA OF VIRGINIA INC
311 PLUS PARK BLVD
SUITE 120
NASHVILLE TN 37217

01

500-481-3
ACCOUNT NO.

CHECKS AND OTHER DEBITS		DEPOSITS AND OTHER CREDITS	DATE	BALANCE
			30	400000
1252			07	398748
935			17	397813
187473			18	210340
750			22	209590
7770	40000	103006	28	264826
750			29	264076
		64333	31	328409

(7-71)

LEBANON - NORENE - MOUNT JULIET

DATE LAST STATEMENT	MINIMUM BALANCE	AVERAGE BALANCE	NUMBER OF DAYS	NO. DEBITS THIS STMT.	NO. CREDITS THIS STMT.	NO. DEBITS THIS MONTH	DATE THIS STATEMENT
1231	8	14	29	4		4	0129821045

BALANCE LAST STATEMENT	TOTAL CREDITS	TOTAL CHECKS	SERVICE CHARGE	BALANCE THIS STATEMENT
328409		245000		83409

RIA OF VIRGINIA INC
311 PLUS PARK BLVD
SUITE 120
NASHVILLE TN 37217

03

900-481-3
ACCOUNT NO.

CHECKS AND OTHER DEBITS	DEPOSITS AND OTHER CREDITS	DATE	BALANCE
		31	328409
150000		04	178409
39200	40000	13	99209
15800		15	83409

LEBANON - NORENE - MOUNT JULIET

DATE LAST STATEMENT	MINIMUM BALANCE	AVERAGE BALANCE	NUMBER OF DAYS	NO. DEBITS THIS STMT.	NO. CREDITS THIS STMT.	NO. DEBITS THIS MONTH	DATE THIS STATEMENT
0129		29	28	9	1	6	02268210 61

BALANCE LAST STATEMENT	TOTAL CREDITS	TOTAL CHECKS	SERVICE CHARGE	BALANCE THIS STATEMENT
83409	500000	475121		108288

RIA OF VIRGINIA INC
311 PLUS PARK BLVD
SUITE 120
NASHVILLE TN 37217

03

900-481-3
ACCOUNT NO.

CHECKS AND OTHER DEBITS	DEPOSITS AND OTHER CREDITS	DATE	BALANCE
		29	83409
1500		05	9009
17800			
55100			
750	500000	09	494259
14000			
67781		11	426478
750		19	425728
309940		23	115788
7500		26	108288

Deposited by Partners other than Winfree

DDA 1799
(7-81)

THE PEOPLES BANK

LEBANON - NORENE - MOUNT JULIET

DATE LAST STATEMENT	MINIMUM BALANCE	AVERAGE BALANCE	NUMBER OF DAYS	NO. DEBITS THIS STMT.	NO. CREDITS THIS STMT.	NO. DEBITS THIS MONTH	DATE THIS STATEMENT
0226		15	32	10	1	8	0330821089

BALANCE LAST STATEMENT	TOTAL CREDITS	TOTAL CHECKS	SERVICE CHARGE	BALANCE THIS STATEMENT
108288	500000	604614		3674

RIA OF VIRGINIA INC
311 PLUS PARK BLVD
SUITE 120
NASHVILLE TN 37217

03

900-481-3
ACCOUNT NO.

CHECKS AND OTHER DEBITS			DEPOSITS AND OTHER CREDITS	DATE	BALANCE
				26	108288
71170				02	37118
1500	15600	60000	500000	04	460018
20900				04	439118
50000				11	389118
309944				12	79174
60000				23	19174
14000				26	5174
1500				30	3674

Deposited by partners other than wintre

(7-81)

THE PEOPLES BANK

LEBANON - NORENE - MOUNT JULIET

DATE LAST STATEMENT	MINIMUM BALANCE	AVERAGE BALANCE	NUMBER OF DAYS	NO. DEBITS THIS STMT.	NO. CREDITS THIS STMT.	NO. DEBITS THIS MONTH	DATE THIS STATEMENT
0330		23	31	15	1	11	043082108

BALANCE LAST STATEMENT	TOTAL CREDITS	TOTAL CHECKS	SERVICE CHARGE	BALANCE THIS STATEMENT
3674	499800	302521		200953

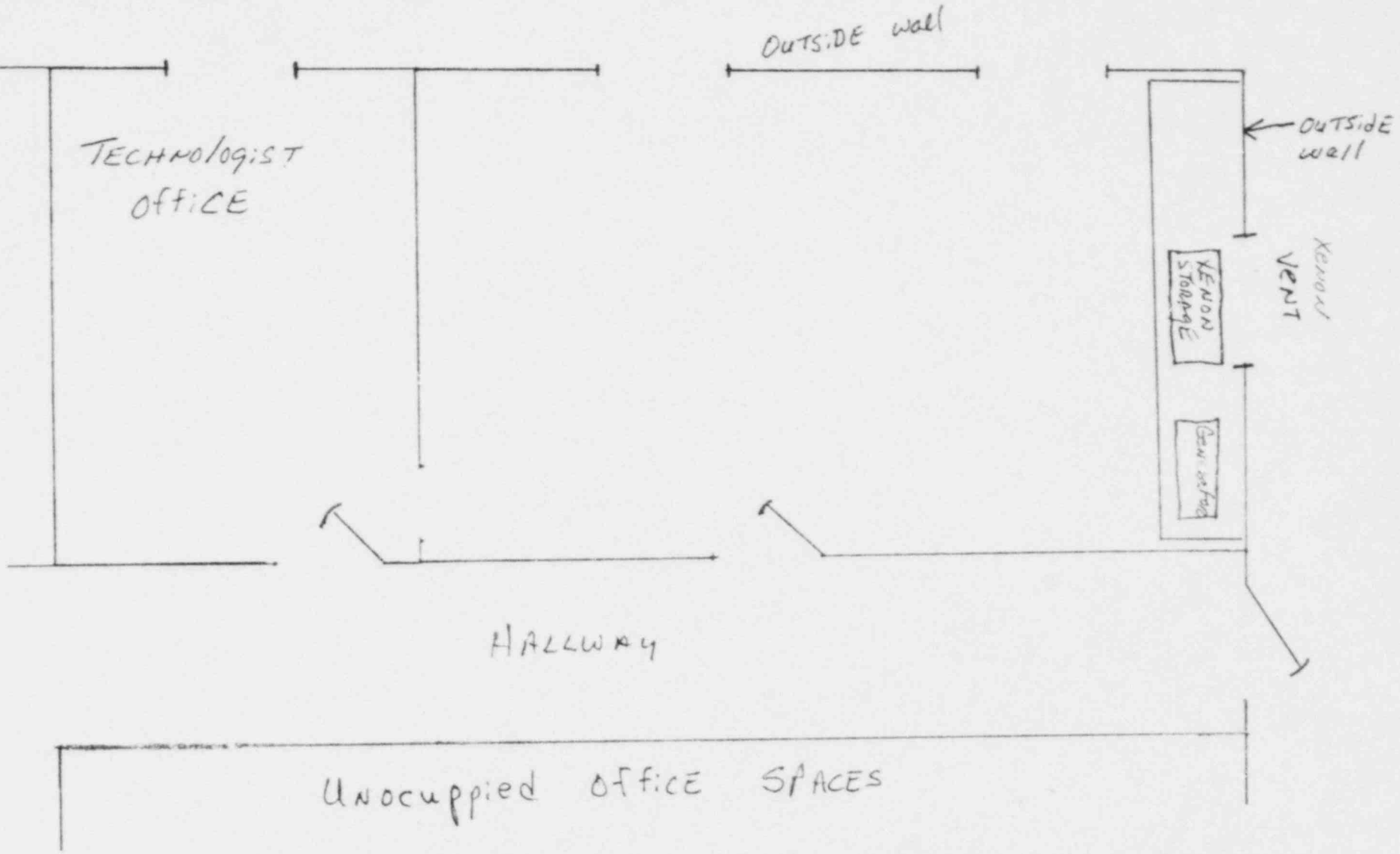
R I A OF VIRGINIA INC
P O BOX 120718
NASHVILLE TN 37212

03

900-481-3
ACCOUNT NO.

CHECKS AND OTHER DEBITS			DEPOSITS AND OTHER CREDITS	DATE	BALANCE
				30	3674
1000				01	2674
5000				02	2326
22967			499800	06	474507
39000	6796	26672		08	402039
35000	44498			08	322541
15000				12	307541
1000				13	306541
9568				15	296973
5000				19	291973
7286	82734			26	201953
1000				29	200953

Deposited by partners other than Winters



These offices will be located at 131 E. Willow Rd. Pennington Gap, Va.
They are on the 2nd floor with no other occupied offices in general area.